

TRANSLATION

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PCT2089FZ015hme	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/EP2004/011978	International filing date (<i>day/month/year</i>) 22.10.2004	Priority date (<i>day/month/year</i>) 22.10.2003
International Patent Classification (IPC) or national classification and IPC A61K33/04		
Applicant BIOSYN ARZNEIMITTEL GMBH		

1.	This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.	
2.	This REPORT consists of a total of <u>6</u> sheets, including this cover sheet.	
3.	This report is also accompanied by ANNEXES, comprising: a. <input type="checkbox"/> (<i>sent to the applicant and to the International Bureau</i>) a total of _____ sheets, as follows: <input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. b. <input type="checkbox"/> (<i>sent to the International Bureau only</i>) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).	
4.	This report contains indications relating to the following items: <input checked="" type="checkbox"/> Box No. I Basis of the report <input checked="" type="checkbox"/> Box No. II Priority <input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability <input type="checkbox"/> Box No. IV Lack of unity of invention <input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement <input type="checkbox"/> Box No. VI Certain documents cited <input type="checkbox"/> Box No. VII Certain defects in the international application <input type="checkbox"/> Box No. VIII Certain observations on the international application	

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

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Box No. I

Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (Rule 12.3 and 23.1(b))
- ☐ publication of the international application (Rule 12.4)
- ☐ international preliminary examination (Rule 55.2 and/or 55.3)
2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
- ☐ the international application as originally filed/furnished
- ☒ the description:
- pages 1-10 _____ as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☒ the claims:
- nos. _____ as originally filed/furnished
- nos.* _____ as amended (together with any statement) under Article 19
- nos.* 1-20 _____ received by this Authority on 16.06.2005 with letter of 16.06.2005
- nos.* _____ received by this Authority on _____
- ☐ the drawings:
- sheets _____ as originally filed/furnished
- sheets* _____ received by this Authority on _____
- sheets* _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. II

Priority

1. ☒ This report has been established as if no priority had been claimed due to the failure to furnish within the prescribed time limit the requested:

☒ copy of the earlier application whose priority has been claimed (Rule 66.7(a)).
☐ translation of the earlier application whose priority has been claimed (Rule 66.7(b)).
2. ☐ This report has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rule 64.1). Thus for the purposes of this report, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:

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Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
1.	Statement		
	Novelty (N)	Claims <u>1-20</u>	YES
		Claims _____	NO
	Inventive step (IS)	Claims <u>1-20</u>	YES
		Claims _____	NO
	Industrial applicability (IA)	Claims <u>1-20</u>	YES
		Claims _____	NO
2.	Citations and explanations (Rule 70.7)		
	<p>1. This report makes reference to the following documents cited in the search report; the numbering will remain the same throughout the proceedings:</p> <p>D1: DATABASE WPI Section Ch, Derwent Publications Ltd., London, GB; Class B04, AN 2002-563534 XP002313189 & KR 2002 012 947 A (JUNG S H) 6 February 2003 (2003-02-06)</p> <p>D2: DATABASE WPI Section Ch, Week 199706 Derwent Publications Ltd., London, GB; Class B04, AN 1997-059687 XP002313314 & JP 08 308561 A (SUMITOMO ELECTRIC IND CO) 26 November 1996 (1996-11-26)</p> <p>D3: US-A-4 512 977 (LUNDY JOSEPH R) 23 April 1985 (1985-04-23)</p> <p>D4: DATABASE WPI Section Ch, Week 198323 Derwent Publications Ltd., London, GB; Class B01, AN 1983-55444K XP002313315 & RO 80 055 A (INTR ANTIBIOTICE) 30 October 1982 (1982-10-30)</p> <p>D5: SENECA H ET AL: "Glucocorticoid therapy in sepsis/shock caused by gram negative</p>		

Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
	<p>microorganisms." JOURNAL OF THE AMERICAN GERIATRICS SOCIETY. NOV 1975, Vol. 23, No. 11 , November 1975 (1975-11), pages 493 502, XP009042536 ISSN: 0002-8614</p> <p>D6: WO 00/12101 A (FORCEVILLE XAVIER; VITOUX DOMINIQUE (FR)) 9 March 2000 (2000-03-09)</p> <p>The numbering of the documents cited in this report, D1-D6, is based on documents D1-D6 cited in the search report. In particular, insofar as is not otherwise noted, the cited text passages of each given document should be taken into consideration.</p> <p><u>Novelty</u></p> <p>2. In terms of formal requirements, claims 1-20 appear to be novel and therefore satisfy the criterion stipulated in PCT Article 33(2).</p> <p>D1 and D2 relate to a medium for cultivating cells and are therefore not suitable for pharmaceutical administration.</p> <p>D3 and D4 relate to a salve or gel composition and therefore not to an aqueous solution.</p> <p><u>Inventive step</u></p> <p>3. D6 is regarded as the prior art closest to the subject matter of claims 1-20.</p> <p>It discloses the use of selenium-containing active substances for treating SIRS (systemic inflammatory response syndrome).</p>

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	<p>The subject matter of claims 1-20 differs from D6 in that a corticoid is used in addition to the selenium-containing active substance.</p> <p>The problem to be solved by the present invention can therefore be regarded as that of "providing a further pharmaceutical preparation that makes it possible to improve the existing therapies for sepsis and/or SIRS" (page 5, paragraph 6).</p> <p>D6 discloses that additional active substances having an anti-inflammatory effect can be combined with the selenium-containing composition.</p> <p>D5 discusses the use of glucocorticoids for treating sepsis. (The abstract of documents D3 and D4 are used for different therapeutic applications, namely for tissue damage and as an anti-acne formulation).</p> <p>A person skilled in the art would not necessarily select a glucocorticoid as an anti-inflammatory substance and combine it with the selenium-containing composition. Furthermore, the description shows a clearly synergistic effect (decrease in mortality in septic patients by up to 80%, as compared to only 20% after administration of the individual substances), which is not suggested at all by D5 or D6. Therefore, claims 1-20 likewise meet the PCT requirements for inventive step (PCT Article 33(3)).</p>